

77. (New) The mammalian host cell of claim 76, further comprising an AAV virion, viral particle, or an rAAV vector.

78. (New) The mammalian host cell of claim 77, wherein said AAV virion, viral particle, or rAAV vector comprises a nucleic acid segment that encodes a therapeutic polypeptide.

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## **2. RESPONSE**

### **2.1 STATUS OF THE CLAIMS**

Claims 41 to 62 were pending at the time of the Action.

Claims 44, 50-56, 58-60 and 62 are cancelled herein without prejudice and without disclaimer.

Claims 41-43, 45-49, 57, and 61 are amended herein.

Claims 63-78 are added herein.

Claims 41-43, 45-49, 57, 61, and 63-78 are now pending in the case.

For the convenience of the Examiner, a marked-up copy of the claims as amended herein is provided in Exhibit A. A clean copy of all pending claims following entry of the foregoing amendments is attached in Exhibit B.

Applicants note for the record that all claims were free from rejection under 35 U. S. C. § 101; claims 41-60 were free from rejection under 35 U. S. C. § 112, 1st paragraph, and claims 41-58, and 60 were free from rejection under 35 U. S. C. § 112, 1st paragraph. Claims 41-45, 47-55, 59 61-62 were free from rejection under 35 U. S. C. § 102.

## **2.2 SUPPORT FOR THE CLAIMS**

Complete support for each of the new claims and the claims as amended herein is provided by the specification and original claims as filed. Applicants certify that no new matter has been introduced as a result of the accompanying amendment.

## **2.3 THE REJECTION OF CLAIMS 61 AND 62 UNDER 35 U. S. C. §112, 1<sup>ST</sup> PARAGRAPH, HAS BEEN OVERCOME.**

Claims 61 and 62 have been rejected under 35 U. S. C. §112, 1<sup>st</sup> paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to make and/or use the invention. Applicants have cancelled claim 62 without prejudice and without disclaimer, and have amended claim 61 to include the ATCC Accession Number of the viral strain deposited under terms of the Budapest Treaty. The required viability statement pursuant to Rule 10.2 was issued on August 28, 2002, and a copy of the statement is attached hereto as Exhibit C. Applicants now believe that all claims are free from further rejection under this section of the Statute, and respectfully requests that the rejection be withdrawn.

## **2.4 THE REJECTION OF CLAIMS 59, AND 61-62 UNDER 35 U. S. C. §112, 2<sup>ND</sup> PARAGRAPH, HAS BEEN OVERCOME.**

Claims 59, 61 and 62 have been rejected under 35 U. S. C. § 112, 2<sup>nd</sup> paragraph, as allegedly being vague and indefinite and failing to particularly point out and claim the subject matter that Applicants regard as their invention. Claims 59 and 62 have been cancelled without prejudice and without disclaimer, and Applicants have amended claim 61 to insert the requested ATCC accession number of the deposited biological specimen, and as such, now believe that these claims are free from further rejection under this section of the Statute.

**2.5 THE REJECTION OF CLAIMS 46, 56-58, AND 60 UNDER 35 U. S. C. §102(B) HAS BEEN OVERCOME.**

Without acquiescing in any way as to the merits of these rejections, for economic concerns, mindful of patent term considerations, and in the interest of proceeding to allowance claims directed to certain commercially-relevant embodiments of the invention, Applicants reserve the right to refile claims to remaining embodiments in one or more continuing applications that claim priority to the present application and its priority claim to the previous provisional application.

Claims 56, 58 and 60 have been cancelled herein; the rejection of these claims is deemed moot. Claims 46 and 57 have been amended to depend from claim 41, a claim previously found free of rejection under the section of the statute. Therefore the rejection of claims 46 and 57 is moot.

**2.6 THE FIRST REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) HAS BEEN OVERCOME.**

As stated above, without acquiescing in any way, and solely to advance claims to certain embodiments of the invention to allowance, existing claims 56, 58 and 60 have been cancelled herein, thus the rejection of these claims under §103(a) is also deemed moot. Claim 57 has been amended to depend from claim 41, a claim previously found free of rejection under the section of the statute. The claimed embodiments directed to viral vectors that comprise a DNA segment isolated from herpes simplex virus ICP27 deletion mutant ATCC PTA-4004, and to host cells and compositions comprising such vectors are neither taught nor fairly suggested by the combination of references cited, and therefore the rejection of the pending claims is improper and should be withdrawn.

**2.7 THE SECOND REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) HAS BEEN OVERCOME.**

Claims 41-48 and 50-55 were rejected as being obvious in view of Dong and Glorioso. Claims 44 and 50-55 have been cancelled herein, thus the rejection of these claims under §103(a) is moot. Claims 41-43 and 45-47 have been amended to particularly point out and claim certain commercially-relevant embodiments of the invention, namely those embodiments concerned with rHSV viral vector compositions that comprise a DNA segment isolated from herpes simplex virus ICP27 deletion mutant ATCC PTA-4004, wherein the segment encodes adeno associated virus *cap* and adeno associated *rep* genes, that are operably linked to a homologous or a heterologous promoter. These embodiments were neither taught nor suggested by the combination of references cited, and therefore the rejection of the pending claims in view of Dong and Glorioso is improper and should be withdrawn. Neither reference discloses or fairly suggests the particular HSV virus, and recombinant viral vectors derived therefrom that have the biological properties of the strain deposited with the ATCC.

**2.8 THE THIRD REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) HAS BEEN OVERCOME.**

Claims 41-48 and 50-60 were rejected as being obvious in view of Dong and Rice. Without acquiescing in any way, and solely in order to proceed claims directed to certain embodiments to allowance, claims 44, 50-56 and 58-60 have been cancelled herein, thus the rejection of these claims under §103(a) is moot. Claims 41-43 and 45-48 have been amended to particularly point out and claim certain commercially-relevant embodiments of the invention, namely those embodiments concerned with HSV virus such as PTA-4004, and the HSV helper vectors and virions and compositions comprising such vectors. These embodiments were neither

taught nor suggested by the combination of references cited, and therefore the rejection of the pending claims in view of Dong and Rice is improper and should be withdrawn. Neither reference discloses or fairly suggests an HSV vector or the DNA sequences derived therefrom that have the biological properties of the strain deposited with the ATCC.

**2.9 THE FOURTH REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) HAS BEEN OVERCOME.**

Claims 46 and 49 were rejected as being obvious in view of Dong and Efstathiou. Without acquiescing in any way, and solely in order to proceed claims directed to certain embodiments to allowance, claims 46 and 49 have been amended herein and the rejection of these claims under §103(a) is moot, since neither reference teaches or suggests the HSV vectors of the invention that possess the biological properties of strain PTA-4004 deposited with the American *Type Culture* Collection under the terms of the Budapest Treaty..

**2.10 CONCLUSION**

Applicants believe this to be a timely and complete response to the outstanding Action, and further believe that all pending claims are free of any rejection under the statutes, and the case is ready for allowance. Applicants expressly reserve the rights to refile claims directed to the remaining embodiments of the invention in subsequent continuing applications. Should the

Examiner have any questions concerning the accompanying amendment, response and related papers, a telephone call to the undersigned Applicants' representative would be appreciated.

Respectfully submitted,

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